



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Shin SHIMAOKA  
Application No.: 10/522,886  
Filed: February 1, 2005  
For: THERAPEUTIC AGENT FOR PSORIASIS

Art Unit: 1616  
Examiner: S. N. Qazi  
Washington, D.C.  
Atty.'s Docket: SHIMAOKA1  
Date: September 22, 2006

Confirmation No. 6595

THE COMMISSIONER OF PATENTS  
U.S. Patent and Trademark Office  
Customer Service Window  
Randolph Building, Mail Stop AF  
401 Dulany Street  
Alexandria, VA 22314

Sir:

RESPONSE UNDER 37 CFR 1.118  
EXPEDITED PROCEDURE  
EXAMINING GROUP 1616

Transmitted herewith is a [XX] SUMMARY OF TELEPHONE INTERVIEW in the above-identified application.

- [ ] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.  
[XX] No additional fee is required.  
[ ] The fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA EQUALS
TOTAL	* 4	MINUS	** 20	0
INDEP.	* 1	MINUS	*** 3	0
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

SMALL ENTITY	
RATE	ADDITIONAL FEE
x 25	\$
x 100	\$
+ 180	\$
ADDITIONAL FEE TOTAL	

OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE
x 50	\$
x 200	\$
+ 360	\$
TOTAL	

- \* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.  
\*\* If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.  
\*\*\* If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity  
Response Filed Within  
[ ] First - \$ 60.00  
[ ] Second - \$ 225.00  
[ ] Third - \$ 510.00  
[ ] Fourth - \$ 795.00  
Month After Time Period Set

Other Than Small Entity  
Response Filed Within  
[ ] First - \$ 120.00  
[ ] Second - \$ 450.00  
[ ] Third - \$ 1020.00  
[ ] Fourth - \$ 1590.00  
Month After Time Period Set

[ ] Less fees (\$ ) already paid for month(s) extension of time on .

[ ] Please charge my Deposit Account No. 02-4035 in the amount of \$ .

[ ] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of \$ .

[ ] A check in the amount of \$ is attached (check no. ).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

BROWDY AND NEIMARK, P.L.L.C.

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Atty. Docket: SHIMAOKA1

In re Application of:	)	Conf. No.: 6595
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Shin SHIMAOKA	)	Art Unit: 1616
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Filed: February 1, 2005	)	Examiner: S. N. Qazi
	)	
Appln. No.: 10/522,886	)	Washington, D.C.
	)	
For: THERAPEUTIC AGENT FOR	)	August 23, 2006
PSORIASIS	)	

SUMMARY OF TELEPHONE INTERVIEW

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop AF  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

This is to make of record a telephone interview between the undersigned and Examiner Sabiha Qazi of September 21, 2006.

During the interview, Examiner Qazi indicated that the arguments made in the amendment filed August 23, 2006, were good arguments, but she was concerned that many vitamin D compounds have calcium mobilizing ability.

In response, it was noted that Ono et al., *Chem. Pharm. Bull.* **45(10)**: 1626-1630, 1997, teach that various analogs of  $1\alpha, 25(\text{OH})_2\text{D}_3$  have been found useful for treating bone diseases such as osteoporosis. In contrast thereto, the claims presently at bar are directed to treating psoriasis.

While the Ono compounds are effective at increasing plasma calcium levels, there is nothing in Ono that even suggests that this indicates the compounds are useful for treating psoriasis. As shown in the table submitted with the August 23 amendment, only some vitamin D derivatives are indicated for treating psoriasis, while others are indicated for treating osteoporosis. Thus, it is clear that vitamin D derivatives are not interchangeable in pharmaceutical effects. Moreover, since osteoporosis is a disease that develops with advancing age, while psoriasis incidence decreases with age, one skilled in the art would not expect that a compound useful for treating osteoporosis would necessarily be useful in treating psoriasis.

Figure 1 of the application as filed clearly shows that the  $IC_{50}$  (mol/L) value of  $1\alpha, 25(OH)_2D_3$  was  $3.05 \times 10^{-8}$  mol/L,. While the  $IC_{50}$  (mol/L) value of ED-71 was  $1.0 \times 10^{-10}$  mol/L. This clearly demonstrates unexpected results from administering ED-71 to treat psoriasis, rather than  $1\alpha, 25(OH)_2D_3$ .

In view of the above, it is respectfully submitted  
that the claims are now in condition for allowance, and  
favorable action thereon is earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

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